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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,929	06/29/2001	Ki-Seung Choi	EF321688773U	9906

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,929	CHOI ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/0/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of IDS, amendment, and response all dated 11-3-03 is acknowledged.

Claims 2-7 have been canceled and new claims 8-22 have been added.

Claim Rejections - 35 USC § 112

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Instant claim recites a sterilization method of killing fungi comprises the step of applying ab anti-algal composition in to the area that is contaminated by algae. It is unclear to the examiner as to how fungi is killed by an anti-algal composition, in particular by applying the composition to an area contaminated by algae. It appears that applicants intended to claim a sterilization method of killing algae and not fungi. A clarification and correction is requested.

Claim Rejections - 35 USC § 103

1. Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 5,278,178 to Hsu and SU 1687261 A1 (hereafter SU '261).

Hsu teaches synergistic microbicidal and biocidal combination compositions comprising 3-isothiazolone mixtures made up of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one and one or more of other antimicrobial compounds. Hsu teaches that the compositions are useful as commercial biocides for effective and broader control of microorganisms (abstract, col. 2, lines 3-54) and recognizes isothiazolone as being effective

against bacteria, fungi and algae (col. 1, L 38-43). Instant specification describes the same compounds taught by Hsu as more preferable isothiazolone compounds (page 6, lines 1-2). Hsu teaches the ratios of isothiazolones as 3:1 (col. 2, lines 56-60). The other antimicrobial compounds of Hsu are listed in col. 3, lines 1-10. Hsu also teaches additives such as solvents, dispersion agents, surfactants (col.3, lines 30-32), which read on the instant additives for emulsion products.

Hsu does not teach the instant combination of isothiazolone and polyhexamethylene guanidine phosphate. However, Hsu suggests that a combination of two isothiazolones and other antimicrobial compounds results in a synergy, which affords a more effective and broader control of microorganisms (col. 2, lines 6-15).

SU '261 teaches polyhexamethylene guanidine gluconate as an active component in disinfecting compositions, useful for improving the disinfecting properties of the composition (abstract). SU '261 does not teach isothiazolone compounds of the instant invention. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine polyhexamethylene guanidine gluconate of SU '261 with the isothiazolone compounds of Hsu because both the references teach compositions containing antimicrobial compounds for disinfecting or preventing microbial contamination. Therefore, one of an ordinary skill in the art would have expected to achieve a synergistic effect in controlling or preventing microbial growth by combining the two disinfectants.

SU '261 does not teach polyhexamethylene guanidine phosphate and instead teaches gluconate salt of the compound. However, absent any criticality, one of an ordinary skill in the art at the time of the instant invention would have expected the same antimicrobial effect with

any salt of polyhexamethylene guanidine i.e., a hydrochloride or gluconate or phosphate salt. With respect to the claimed ratio of isothiazolone and polyhexamethylene guanidine salt, it would have been obvious for one of an ordinary skill in the art to optimize the ratios of different antimicrobial agents in composition containing combination of antimicrobials, such that maximum antimicrobial effect is achieved.

2. Claims 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 5,278,178 to Hsu and SU 1687261 A1 (hereafter SU '261) in view of JP 10175809(hereafter JP '809, submitted on PTO-1449).

The teachings of Hsu and SU '261 have been discussed above. Neither teaches a combination of isothiazolone and polyhexamethylene guanidine phosphate. However, Hsu suggests that a combination of isothaizolones and other antimicrobials result in a synergistic effect and provide broader control over microorganisms.

JP '809 teaches industrial antimicrobial compositions comprising isothaizolones and polyhexamethylene guanidine hydrochloride and suggests that the synergistic composition is effective against bacteria, fungi, yeast, algae and actinomycetes.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine isothiazolones of Hsu and polyhexamethylene guanidine gluconate of SU '261, with an expectation to achieve a synergistic effect in preventing and controlling microbial growth. Further, optimizing the amounts of individual antimicrobial agents in a composition so as to achieve a maximum antimicrobial effect would have been obvious for one of an ordinary skill in the art.

Although JP '809 teaches hydrochloride salt of polyhexamethylene biguanidine and not a phosphate salt, as explained above, absent any criticality one of an ordinary skill in the art at the time of the instant invention would have expected the same antimicrobial effect with any salt of polyhexamethylene guanidine i.e., a hydrochloride or gluconate or phosphate salt.

Response to Arguments

Applicant's arguments filed 11-3-03 have been fully considered but they are not persuasive.

Examiner has considered applicants' arguments and the results presented in Declaration under 1.132. Examiner notes applicants' statement that a Declaration supporting the anti-algal effect of the claimed combination of compounds is being prepared and will be presented.

HSU and Gambitskii: Applicants argue that on contrary to examiner's statement that one of an ordinary skill in the art would have expected the same antimicrobial effect with any salt of PHMB i.e., hydrochloride or gluconate or phosphate salt, the present results show that phosphate salt of PHMG surprisingly outperformed compositions having PMHM gluconate and isothiazolone. In particular, applicants refer to the lower MIC than comparative examples against Pencillium citrinum, P. vulgaris, C. albicans, and A. niger. Applicants argue that Hsu and Gambitskii completely fail to teach or suggest the unexpected results shown. Further, applicants also argue that neither reference teach that PHMB gluconate has any anti-fungal or anti-algal activity.

Applicants' arguments have been considered but not found persuasive. The present data shows higher antimicrobial activity of phosphate salt of PHMG + 3-isaothiazolone, over that of a

hydrochloride or a gluconate salt in combination of 3-isothiazolone. However, the phosphate salt is shown to be more active than the other salts only against certain bacteria (K. pneumoniae, P.vulgaris & A. niger s), but does not show any more activity than the other two salts against other species (S. typhimurium, P.aeruginosa, S.aureus, R.oryzae). None of the results are directed anti-algal activity. Further, the instant "biocide" composition includes not antibacterial and anti-fungal but also anti-protozoal effect. Thus, the combination of claimed compounds exhibit unexpected synergy only against certain microbial species. Further, with respect to applicants' argument that Gambitskii does not teach anti-algal and anti-fungal effect of PHMB gluconate, examiner has withdrawn the rejection of new claims directed to anti-algal or anti-fungal effect as being obvious over Hsu and Gambitskii. Instead, the claims directed to anti-algal and anti-fungal effect of the claimed combination are rejected as being obvious over Hsu, Gambitskii in view of Toshimasa. Applicants argue that the cited references fail to teach anti-algal or anti-fungal activity of PHMB hydrochloride. However, applicants' arguments are not persuasive because JP '809 clearly teaches industrial antimicrobial compositions comprising isothaizolones and polyhexamethylene guanidine hydrochloride and suggest that the synergistic composition is effective against bacteria, fungi, yeast, algae and actinomycetes. Thus, one of an ordinary skill in the art would have expected a combination of isothiazolone and PHMB hydrochloride to be effective against bacteria as well as fungi and algae. In this regard, the results presented in the declaration are not are not in the same scope of the instant claims for at least the anti-algal effect. Therefore, the rejection has been maintained.

With respect to the IDS submitted 11-3-03, applicants have not indicated the dates of the references for ATCC cultures recited under other documents. Upon submission of the dates, examiner will consider the references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S Channavajjala
Examiner
Art Unit 1615
February 24, 2004

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600